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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,866	02/01/2001	David Thomas	PNJ-001	3286

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DARBY & DARBY
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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/773,866	THOMAS ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 9/2/04; 11/3/03

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 21-30

4a) Of the above claim(s) _____ is/are withdrawn from consideration. 25-28

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 21-24, 29, 30

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Species A (anti-CD40 antibody), filed 9/2/04 is acknowledged.

Applicant request that Species A (anti-CD40 antibody) and Species B (bispecific antibody) do not warrant separate examination and search because both species call for an antibody specific to CD40.

Applicant is reminded that anti-CD40 antibodies and bispecific anti-CD40 antibodies (which encompass binding different CD40-specific epitopes or antigens) do differ in physiochemical structures of differ and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable.

As indicated previously, should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Claims 21-24 and 29-30 are under consideration in the instant application.

Claims 25-28 have been withdrawn have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species; the requirement having been traversed

Claims 1-20 have been canceled.

2. Applicant's arguments, filed 11/3/03 and 9/2/04, concerning the previous rejection of record, are acknowledged, however these arguments are rendered moot in view of the new claims and New Grounds of Rejection.

3. Applicant's amendment, filed 11/10/03 and reiterated in the amendment filed 9/2/04 have deleted the previous references to Table 1 (page 19, line 2) and Table 2 (page 22, line 14) of the instant specification.

4. Formal drawings, filed 7/15/02 have been submitted which fail to comply with 37 CFR 1.84.
Please see the form PTO-948 previously mailed 9/3/02.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES
A. Correction of Informalities -- 37 CFR 1.85
New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the

mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The previous rejections under 35 U.S.C. § 112, first paragraph, written description and enablement, with respect to the previous recitations encompassing "agonist anti-CD40 molecules" as well as "analogues or homologues thereof or a peptide, oligonucleotide, peptidomimetic or an organic compound which binds to the same epitopes as such antibodies" have been withdrawn in view of the canceled claims.

7. Claims 21-24 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In vitro and animal model studies have not correlated well with in vivo clinical trial results in patients. Since the therapeutic indices of biopharmaceutical drugs can be species- and model-dependent, it is not clear that reliance on the in vitro experimental observations on the binding of anti-CD40 antibodies accurately reflects the relative efficacy of the claimed therapeutic strategy to induce antigen specific cytotoxic T cell responses by administering agonistic anti-CD40 antibodies in the absence of antigen.

Pharmaceutical therapies in the absence of in vivo clinical data are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

The specification does not adequately teach how to induce antigen specific cytotoxic T lymphocyte responses in the absence of administering an antigen. For example, Melief et al. (US 2003/0022860) describe Experiments which show that CD40-triggering can prime cytotoxic T cell responses in vivo (see paragraph [0045]. To this end, mice were injected with E1A/IFA vaccine in combination with the activating anti-CD40 antibody. Mice that received this combination mounted strong E1A-specific CTL response, whereas mice that received the E1A/IFA vaccine or antibody alone did not. The specification does not teach how to extrapolate data obtained from in vitro binding inhibition assays to the development of effective in vivo therapeutic methods that can induce antigen specific T lymphocytes in the absence of a specific antigen. Therefore, it is not clear that the skilled artisan could predict the efficacy of inducing an antigen specific cytotoxic lymphocytes by administering anti-CD40 antibody in the absence of an antigen.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, making and using anti-CD40 antibodies in the absence of antigen would provide the antigen-specific cytotoxic T cell response encompassed by the claimed methods would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

8. Claims 21-24 and 29-30 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed:

"an antibody or binding fragment thereof, that binds to CD40 on human APCs without blocking of CD40L".

Applicant's amendment, filed 11/10/03, directs support to pages 16 and 19-21 and asserts that no new matter has been added.

It is acknowledged that page 16, lines 11-20 describe the Induction of Mature Dendritic Cells with anti-CD40 antibodies induced an influenza-matrix peptide specific autologous cytotoxic $CD8^+$ T lymphocytes.

It is presumed that applicant is relying upon this description to read on the limitation of "wherein the antibody is capable of inducing an APC-mediated antigen specific human cytotoxic T lymphocyte response".

For examination purposes, the recitation of "inducing an APC-mediated antigen specific human cytotoxic T lymphocyte response" simply reads on the well-known induction of immune responses (e.g. antigen-specific) by antigen presenting cells (APCs) reads on agonistic antibodies, that is, agonistic anti-CD40 antibodies that stimulate (i.e. act as costimulators) and does not read on any particular antigen-specific property. Antigen provides the antigen specificity in such circumstances encompassing antigen processing and antigen presentation.

Pages 19-21 of the instant specification describes Example 3, which Assays the Ability of the CD40 reactive Antibody Clones to Drive Maturation, IL-12p70 and Priming for CTL Activation of Immature DC, that is CD40-specific antibodies had an increased ability of these cells to induce a flu peptide directed $CD8^+$ T cell response.

At best, Example 4 on pages 22-23 of the instant specification describes Analysis of the Inhibition of the Binding of sCD40L to CD40 by the Anti-CD40 Antibody Samples. "In this experiment clone 4 blocked binding of CD40-Fc to CD40L on the T cells for 88%, clone 7 and 64 for respectively 16% and 25%. Although there was no absolute correlation between the performance of the antibodies in the CD maturation and the THP-1 assay and their ability to block sCD40L binding to CD40, all the clones that did not block this interaction were non-responders in both assays (data not shown.)."

In contrast to applicant's assertions, there is insufficient direction for the written description for the above-mentioned limitation encompassing "an antibody or binding fragment thereof, that binds to CD40 on human APCs without blocking of CD40L".

The exemplified antibody producing clones in Example 4 block CD40L binding at various levels, Further, applicant's attempt to rely upon a generic disclosure and possibly a single or limited species of CD40-binding antibodies that have varying degrees of inhibiting CD40L-binding, but do not provide for anti-CD40 antibody producing clones which have the property encompassed by the recitation of without blocking of CD40L, now recited and, in turn, "induce an APC-mediated antigen specific human cytotoxic T lymphocyte response".

Applicant is claiming a subgenus not supported by the specification as-filed.

The specification as filed does not provide a written description or set forth the metes and bounds of this phrase. The specification does not provide sufficient blazemarks nor direction for the instant methods encompassing the above-mentioned "limitation", as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

9. Applicant's cancellation of claims have obviated the previous rejections under 35 U.S.C. § 112, second paragraph.

10. Claim 24 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 contains the trademark or trade name "DeImmunized™" Where a trademark or trade name is used in a claims as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 USC 112, second paragraph, See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark or the trade name "DeImmunized™" is used to identify or describe a product or possibly a product-by-process, and accordingly, the identification or the description is indefinite. The relationship between a trademark or tradename and the product it identifies may be uncertain and arbitrary. The formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark or tradename.

Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 21-24 and 30 are rejected under 35 U.S.C. § 102 (e) as being anticipated by Melief et al. (US 2003/0022860 A1; Jan. 30, 2003) (see entire document).

Melief et al. teach methods of treating tumors or infectious diseases comprising administering anti-CD40 antibodies or fragments thereof, including monoclonal, chimeric, humanized, human, DEIMMUNISED and single chain antibodies (see paragraphs [0029] – [0034] and a CTL activating peptide by generating or enhancing immune responses via the CD40 pathway on dendritic cells. (see Background of the Invention, Summary of the Invention, and Making and Using the Invention). Methods of administration by injection are described (see paragraph [0036]).

Melief et al. employs the activating anti-CD40 antibody FGK-45 (see paragraph [[0045]). Although the reference is silent about the claimed recitation of "without blocking binding of CD40L to CD40", it appears that Melief et al. teach agonistic anti-CD40 antibodies, including the specific FGK-45 specificity. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. The burden is on the applicant to establish a patentable distinction between the claimed and referenced agonistic anti-CD40 antibodies.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods of stimulating immune responses to tumors and infectious diseases with agonistic anti-CD40 antibodies and a CTL activating peptide. Unlike the current claims, the prior art teaches the provision of a CTL activating peptide, which, in turn, induced a specific CTL mediated immunity.

14. Claims 21-24 and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Melief et al. (US 2003/0022860 A1; Jan. 30, 2003) in view of Zhou et al. (Hybridoma 18: 471 - 478, 1999) (of record) AND/OR Caux et al. (Research in Immunology 145: 235-239, 1994) (of record) AND/OR Katira et al. (Leukocyte Typing V, Schlossman et al. (Ed.), Oxford University Press, Oxford 1995, page 554) (of record) AND/OR Schwabe et al. (Hybridoma 16 : 217 – 226, 1997) (of record).

Melief et al. teach methods of treating tumors or infectious diseases comprising administering anti-CD40 antibodies or fragments thereof, including monoclonal, chimeric, humanized, human, DEIMMUNISED and single chain antibodies (see paragraphs [0029] – [0034] and a CTL activating peptide by generating or enhancing immune responses via the CD40 pathway on dendritic cells. (see Background of the Invention, Summary of the Invention, and Making and Using the Invention). Methods of administration by injection are described (see paragraph [0036]).

Melief et al. employs the activating anti-CD40 antibody FGK-45 (see paragraph [[0045]). Although the reference is silent about the claimed recitation of "without blocking binding of CD40L to CD40", it appears that Melief et al. teach agonistic anti-CD40 antibodies, including the specific FGK-45 specificity. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. The burden is on the applicant to establish a patentable distinction between the claimed and referenced agonistic anti-CD40 antibodies.

In addition, the following references Zhou et al., Caux et al., Katria et al. and Schwabe et al. all teach that a number of agonistic anti-CD40 antibodies were known and employed by the ordinary artisan at the time the invention was made. Furthermore, these references teach that such agonistic anti-CD40 antibodies encompass stimulatory anti-CD40 antibodies that block and do not block CD40 : CD40L interactions.

For example, Zhou et al. teach the agonistic anti-human CD40 antibody 5C11, which triggers the generation, proliferation and maturation of dendritic cells from peripheral blood monocytes (see entire document, including the Abstract).

For example in a Workshop on a panel of anti-CD40 antibodies, Katira et al. identify various epitopes on CD40, including the existence of several functional epitopes that support the presence of more than one ligand for this important receptor (see entire document on page 554).

Schwabe et al. teach the characterization of anti-CD40 antibodies, which also supports the presence of various epitopes, not all of which rely upon the CD40L binding region, as recognized by agonistic anti-CD40 antibodies. Further, Schwabe teach that the mimetic effects binding of the CD40L epitope was not of advantage (see Abstract). Schwabe et al. teach the advantages of multiple epitopes in regulating immune interactions and responses (see Discussion).

Given the number of anti-CD40 antibodies at the time the invention was made, it would have been obvious to the ordinary artisan at the time the invention was made to employ (e.g. administer, inject) agonistic anti-CD40 antibodies, including those that inhibit CD40L binding and those that do not inhibit CD40L binding to CD40 to stimulate the desired antigen-specific immune responses directed toward antigens associated with treating tumor or infectious diseases, as taught by Melief et al. at the time the invention was made. The claimed functional limitations would be intrinsic or expected properties of the referenced methods of stimulating immune responses to tumors and infectious diseases with agonistic anti-CD40 antibodies, including those agonistic antibodies that do not inhibit CD40:CD40L interactions, as taught by the secondary references, and a CTL activating peptide. Unlike the current claims, the prior art teaches the provision of a CTL activating peptide, which, in turn, induced a specific CTL mediated immunity.

It was well known to use of chimeric, humanized, DeImmunized, human antibodies as well as antibody fragments at the time the invention was made, as acknowledged by Melief et al. In addition to the decreased immunogenicity of recombinant antibodies and antibody fragments, the use of the claimed antibodies and antibodies fragments were all well known and practiced at the time the invention in a wide variety of assays and methods, including detection and therapeutic modalities.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. Claim 28 is are rejected under 35 U.S.C. § 103(a) as being unpatentable over Melief et al. (US 2003/0022860 A1; Jan. 30, 2003) in view of Zhou et al. (Hybridoma 18: 471 - 478, 1999) AND/OR Caux et al. (Research in Immunology 145: 235-239, 1994) AND/OR Katira et al. (Leukocyte Typing V, Schlossman et al. (Ed.), Oxford University Press, Oxford 1995, page 554) AND/OR Schwabe et al. (Hybridoma 16 : 217 – 226, 1997)

as applied to claims 21- 24 and 29 above and further in view of Maraskovsky et al. (U.S. Patent No.) and further in view of Maraskovsky et al. (U.S. Patent No. 6,497,876).

Melief et al. in view of Zhou et al., Caux et al., Katira et al. and Schwabe et al. differ from the claimed methods by not disclosing the well known use of interferon-γ to treat patients with tumors and infections in combination therapy.

Maraskovsky et al. teach the well known use of interferon-γ to treat patients with tumors and infections, including the administration of such cytokines as interferon-γ in combination therapy (e.g. see column 2, paragraph 2 and Preparation of Antigens on columns 10-11). It is noted that the teachings of Maraskovsky et al. are directed to the use of stimulating antigen specific dendritic cells via stimulating the CD40:CD40L pathway, which in turn, provides further motivation and expectation of success of combining interferon-γ with modalties that rely upon stimulating CD40 pathways in the generation of antigen-specific immune responses to antigens (e.g. tumor- / infection-related antigens).

Therefore, it would have obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of Maraskovsky et al. to those of combination of references which stand for the administration of agonistic CD40 antibodies, including those that do not bind the CD40L binding epitope on CD40, to obtain combination therapies combining the administration of both agonistic anti-CD40 antibodies and interferon-γ. According to references, a person of ordinary skill in the art would have been motivated to combine both agonistic anti-CD40 antibodies and interferon-γ to generate antigen-specific CTL responses to antigens of interest, since both reagents were able to increase such immune response and combination was known and practiced at the time the invention was made, as evidence by Maraskosky et al.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, PhD.
Primary Examiner
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December 27, 2004